UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

LAVETA JORDAN, et al., Plaintiffs, v. BAYER CORP., BAYER HEALTHCARE LLC, BAYER ESSURE, INC., (f/k/a CONCEPTUS, INC.), BAYER HEALTHCARE PHARMACEUTICALS INC., BAYER A.G., Defendants.	Case No. 4:17-cv-00865 **JURY TRIAL DEMANDED**

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

The Petition is meritless, and other courts have rejected virtually identical claims, which are preempted by federal law and do not meet federal pleading standards. *See, e.g.*, *Norman v. Bayer Corp.*, No. 3:16-cv-00253 (JAM), 2016 WL 4007547 (D. Conn. July 26, 2016) (dismissing all claims with prejudice); *De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085 (N.D. Cal. 2016) (dismissing all claims with leave to amend certain claims, after which plaintiff voluntarily dismissed case); *Richardson v. Bayer HealthCare Pharms. Inc.*, No. 4:15-cv-00443, 2016 WL 4546369 (D. Idaho Aug. 30, 2016) (dismissing almost all claims, after which plaintiff voluntarily dismissed case); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 838-39 (E.D. Pa. 2016) (dismissing almost all claims); *see also McLaughlin v. Bayer Corp.*, Nos. 14-7315 et al., 2017 WL 697047 (E.D. Pa. Feb. 21, 2017) (further narrowing claims).[1]

Plaintiffs are engaging in forum shopping because these other courts across the country have rejected virtually identical claims. These courts have had no trouble dismissing the claims at issue because, at bottom, Plaintiffs are attempting to second guess the United States Food & Drug Administration ("FDA"). *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001); *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204-08 (8th Cir. 2010); *see also* 21 U.S.C. §§ 360k(a), 337(a). FDA has the exclusive authority to regulate Class III medical devices like

[1] Plaintiffs have fared no better in state courts. *See Medali v. Bayer HealthCare LLC*, No. RG15771555 (Cal. Super Ct. Feb. 16, 2016) (demurrer sustained with leave to amend certain claims) (order attached as Exhibit A to concurrently filed Request for Judicial Notice ("RJN")); *Noris v. Bayer Essure, Inc.*, No. BC589882, (Cal. Super. Ct. Apr. 26, 2016) (same) (transcript excerpts attached as RJN Ex. B); *Williams v. Bayer Corp.*, No. 15BA-CV02526 (Mo. Cir. Ct. July 18, 2016) (complaint dismissed with prejudice) (RJN Ex. C); *Lance v. Bayer Essure Inc.*, RG16809860 (Cal. Super. Aug. 2, 2016) (RJN Ex. D) (demurrer sustained in part). *But see Johnson v. Bayer Corp.*, No. 1622-CC01049-01 (Mo. Cir. Ct., 22nd Jud. Cir., Dec. 20, 2016) (applying wrong legal standard and denying motion to dismiss)

Essure, and has decided—numerous times—that Essure is safe and effective. FDA has balanced the benefits and risks of the device and recently confirmed that "Essure remains an appropriate option for the majority of women seeking a permanent form of birth control." RJN Ex. F, U.S. Food and Drug Admin., *FDA Takes Additional Action to Better Understand Safety of Essure, Inform Patients of Potential Risks*, News Release (Feb. 29, 2016), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm488313.htm ("FDA News Release").

Plaintiffs disagree with FDA and are scouring the country for a court that will agree with them. This Court should rebuff their efforts. Here, only eight of the Plaintiffs (the "Missouri Plaintiffs") allege any connection to Missouri.[2] The other 86 plaintiffs (the "non-Missouri Plaintiffs") have *no* connection at all to Missouri and should not be suing in this State because there is no personal jurisdiction over their claims. These 86 plaintiffs are not citizens of Missouri and do not allege that they received the product at issue in Missouri or were injured in Missouri. None of the Defendants, Bayer Corporation, Bayer HealthCare LLC, Bayer Essure Inc., and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer"), is based in Missouri either.

For the same reasons articulated by Judge Webber in *Addelson v. Sanofi S.A.*, No. 4:16-cv-01277, 2016 WL 6216124, at *2-4 (E.D. Mo. Oct. 25, 2016)—and by a groundswell of well-reasoned decisions by other courts around the country, *see, e.g.*, *In re Bard IVC Filters Prods. Liab. Litig.*, No. CV-16-02853, 2016 WL 6393596, at *2-6 (D. Ariz. Oct. 28, 2016); *Aclin v. PD-RX Pharms. Inc.*, 2016 WL 3093246, at *2-8 (W.D. Okla. June 6, 2016); *In re Zofran (Ondansetron) Prods. Liab. Litig.*, 2016 WL 2349105, at *2-5 (D. Mass. May 4, 2016); *Kraft v.*

[2] These include the seven Missouri citizens and Plaintiff Jennifer Dishbein, who alleges her device was placed in Missouri.

Johnson & Johnson, 97 F. Supp. 3d 846, 849-55 (S.D.W.V. 2015)—this Court should first dismiss the non-Missouri Plaintiffs' claims for lack of personal jurisdiction, and then keep subject matter jurisdiction over the remaining Missouri plaintiffs' claims who are completely diverse from the Bayer defendants. Even the Missouri Supreme Court recently made clear that out-of-state defendants are not subject to personal jurisdiction in Missouri—whether general jurisdiction, specific jurisdiction, or "consent" to personal jurisdiction—with respect to claims of plaintiffs who have no connection to Missouri. *See generally State ex rel. Norfolk S. Ry. v. Dolan*, SC95514, slip. op. (Mo. banc Feb. 28, 2017) (RJN Ex. E).

If the Court does not dismiss the non-Missouri Plaintiffs' claims for lack of personal jurisdiction now, it should at least await guidance from (1) the Supreme Court's pending decision in *Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco County*, No. 16-466, 2017 WL 215687 (U.S.) ("*BMS*"), (2) the Eighth Circuit's pending decision in *Robinson v. Pfizer, Inc.*, No. 16-2524, and (3) the Missouri Supreme Court in *State ex rel. Bayer Corp. v. The Hon. Joan L. Moriarty*, No. SC96189 (Mo.), in all three of which the underlying personal jurisdiction and subject matter jurisdiction questions at issue here are presented. *See* Notice of Removal (filed herewith).

BACKGROUND

A. Statutory And Regulatory Background

Congress has spoken. The Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA") grant FDA exclusive authority to regulate medical devices and create a comprehensive statutory "regime of detailed federal oversight." *Riegel*, 552 U.S. at 316. To alleviate the "undu[e] burden[]" of differing state regulation, Congress adopted a "general prohibition on non-Federal regulation" of medical devices by incorporating an express-preemption clause into the MDA. H.R. Rep. No. 94–853, at 45 (1976); *Brooks v. Howmedica,*

Inc., 273 F.3d 785, 797 (8th Cir. 2001) ("need for national uniformity in product regulation" was "one of the explicit goals of the MDA"). Accordingly, no state may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable . . . to the device" under federal law. 21 U.S.C. § 360k(a).

Under the MDA, devices that "support[] or sustain[] human life" or "present[] a potential unreasonable risk of illness or injury" are designated "Class III" devices. 21 U.S.C. § 360c(a)(1)(C)(ii). Innovative Class III devices, including Essure, must receive pre-market approval (PMA) before they may be brought to market. *Buckman*, 531 U.S. at 344. FDA grants PMA only if it "finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360e(d)).

The agency's review "is a rigorous process," in which the manufacturer submits "a multivolume application." *Riegel*, 552 U.S. at 317-18 (internal quotations omitted). Balancing benefits and risks, the "FDA spends an average of 1,200 hours reviewing each application," and will "grant[] premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.*; *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1336 (10th Cir. 2015), *cert. denied*, 136 S. Ct. 796 (2016). The materials a "manufacturer must furnish" include "detailed information about the device's testing, design, components, performance standards, manufacturing, packaging, and labeling." *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 74 (2d Cir. 2006). FDA then scrutinizes these applications, "'weigh[ing] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360c(a)(2)(C)).

FDA reviews a device's proposed labeling, which includes the Instructions for Use (for physicians) and Patient Information Booklet (for patients), as part of the PMA process. It

"evaluates safety and effectiveness under the conditions of use set forth on the label," and "must determine that the proposed labeling is neither false nor misleading" before granting approval. *Id.* at 318 (citing 21 U.S.C. §§ 360c(a)(2)(B), 360e(d)(1)(A)). FDA may also specify requirements that apply to the training of practitioners who use the device, and these requirements must appear in the FDA-approved labeling. 21 U.S.C. § 360j(e). Once a device has been approved, a manufacturer cannot make changes to the labeling without FDA permission, 21 U.S.C. §§ 360e(d)(6)(A)(i), under "largely the same criteria" as the initial application. *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6), 21 C.F.R. § 814.39(c)). The statute likewise "forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* (citing 21 U.S.C. § 360e(d)(6)(A)(i)).

B. Factual Background

FDA has long recognized that Essure is a safe and effective method of permanent female contraception. Essure consists of two "micro-inserts" that are placed in a patient's fallopian tubes by her doctor. In 2002, FDA granted Essure PMA as a Class III device, and FDA has never withdrawn or suspended that PMA. *See* FDA, Premarket Approval Order for the Essure System (RJN, Ex. G at 4); Summary of Safety and Effectiveness Data for Essure System (RJN Ex. H); FDA, Essure System PMA Supplements (RJN Ex. I); FDA, Essure "Regulatory History" (RJN Ex. J). Rather, FDA has granted numerous supplemental approvals, including as recently as November 2016. FDA, PMA Supplements (RJN Ex. I). FDA repeatedly has reviewed and approved Essure's design, construction, manufacturing, testing, training requirements, warnings, instructions for use, patient information, and all other labeling. FDA, Premarket Approval Order for the Essure System (RJN Ex. G at 4); Summary of Safety and Effectiveness Data for Essure System (RJN Ex. H); Professional Labeling (2002) ("2002 IFU") (RJN, Ex. K); Health Care

Provider Instructions for Use (2013) ("2013 IFU") (RJN, Ex. L); ESS305 Post-Approval Study: 12 month interim report (RJN, Ex. M). In fact, FDA recently rejected challenges to the device, reconfirming that "FDA believes Essure remains an appropriate option for the majority of women seeking a permanent form of birth control." FDA News Release (Feb. 29, 2016) (RJN, Ex. F).

Plaintiffs in this case allege that they received Essure from their doctors and experienced a wide variety of injuries, including hysterectomy, unintended pregnancy, miscarriage, heavy menstrual bleeding, migraines, seizures, chronic back and pelvic pain, abdominal pain, pain during intercourse, fibromyalgia, ovarian cysts, and depression. Pet. ¶¶ 466-994.

ARGUMENT

Plaintiffs' claims are preempted by federal law, and they fail to meet federal pleading standards. Numerous courts have rejected nearly identical claims, *see supra* at 1, and this Court should do the same, *see Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.* 623 F.3d 1200, 1205-08. As an initial matter, however, all but twelve of the Plaintiffs should not even be suing in Missouri, because they have no connection at all to the State. The Court should dismiss these Plaintiffs' claims for lack of personal jurisdiction, *see* Part I, or for *forum non conveniens*, *see* Part II. The Court also should dismiss all Plaintiffs' claims for failure to state a claim, *see* Parts III-IV.

I. THE NON-MISSOURI PLAINTIFFS' CLAIMS SHOULD BE DISMISSED FOR LACK OF PERSONAL JURISDICTION.

Bayer is not subject to personal jurisdiction with respect to the claims of the 86 non-Missouri Plaintiffs. *See* Fed. R. Civ. P. 12(b)(2). "To survive a motion to dismiss for lack of personal jurisdiction, a plaintiff must make a prima facie showing that personal jurisdiction exists." *K-V Pharm. Co. v. J. Uriach & CIA, S.A.*, 648 F.3d 588, 591 (8th Cir. 2011). The

plaintiff must plead "sufficient facts to support a reasonable inference that the defendant[] can be subjected to jurisdiction within the state." *Id.* at 591-92.

Here, the 88 non-Missouri Plaintiffs do not plead facts to show either general or specific jurisdiction over Bayer in Missouri. *See, e.g.*, *Daimler AG v. Bauman*, 134 S. Ct. 746, 760, 761 n.19 (2014); *Norfolk S.*, SC95514, slip op. (RJN Ex. E); *Addelson v. Sanofi S.A.*, No. 4:16CV01277, 2016 WL 6216124, at *3-4 (E.D. Mo. Oct. 25, 2016); *In re Bard IVC Filters Prods. Liab. Litig.*, No. CV-16-02853, MDL 15-2461, 2016 WL 6393596, at *6 (D. Ariz. Oct. 28, 2016); *Aclin v. PD-RX Pharms. Inc.*, No. 5:15-CV-00561, 2016 WL 3093246, at *3-8 (W.D. Okla. June 1, 2016); *In re Zofran (Ondansetron) Prods. Liab. Litig.*, No. 1:15-md-2657, 2016 WL 2349105, at *3-5 (D. Mass. May 4, 2016). The 86 non-Missouri Plaintiffs cannot "piggyback" on the specific jurisdiction of the eight Missouri Plaintiffs: "Supplemental specific jurisdiction does not exist; personal jurisdiction must exist separately for each claim." *Addelson*, 2016 WL 6216124 at *3-4 & n.3 (citing cases); *see, e.g.*, *Bard*, 2016 WL 6393596, at *5-6; *Level 3 Commc'ns, LLC v. Ill. Bell Tel. Co.*, No. 4:13-CV-1080, 2014 WL 50856, at *2 (E.D. Mo. Jan. 7, 2014), *vacated in part on other grounds*, 2014 WL 1347531 (E.D. Mo. Apr. 4, 2014).

Accordingly, there is no basis—consistent with federal Due Process—to exercise personal jurisdiction over the non-Missouri Plaintiffs' claims. *See* Briefing in *Robinson* (Pfizer Opening Br. § II; Chamber of Commerce of the United States and Pharmaceutical Research and Manufacturers of America ("PhRMA") Amicus Br. §§ A-B); American Tort Reform Association Amicus Br. §§ II-III; Missouri Organization of Defense Lawyers Amicus Br. §§ II-IV; Washington Legal Foundation Amicus Br. §§ I-III) (attached as Exhibit F-J to Notice of Removal (filed herewith).

A. Bayer Is Not Subject To General Personal Jurisdiction In Missouri.

General personal jurisdiction, which extends to claims "unrelated to the defendant's contacts with the forum state," exists only when the defendant's unrelated contacts are "'continuous and systematic,'" such that the defendant is "'essentially at home'" in that state. *Viasystems, Inc. v. EBM-Papbst St. Georgen GmbH & Co., KG*, 646 F.3d 589, 595 (8th Cir. 2011). A corporate defendant is subject to general jurisdiction in the states where it is incorporated and has its principal place of business. *Daimler*, 134 S. Ct. at 761 n. 19. It can be subject to general jurisdiction in another state only in an "exceptional" case, where its "operations" are "so substantial and of such a nature as to render the corporation at home." *Id.*; *see also Keeley v. Pfizer Inc.*, No. 4:15CV00583, 2015 WL 3999488, at *2 (E.D. Mo. July 1, 2015) ("The Supreme Court has limited general jurisdiction for a corporation to its place of incorporation or principal place of business except in an 'exceptional case.'").

Here, no Defendant is incorporated in Missouri or has its principal place of business in Missouri. *See* Notice of Removal ¶¶ 24-28. And Plaintiffs have not pleaded facts that demonstrate that this is an "exceptional" case in which Defendants are nonetheless "at home" in Missouri. *Daimler*, 134 S. Ct. at 761 n. 19. Plaintiffs allege that Bayer conducts "substantial business activities" in Missouri. Pet. ¶ 167. But it is well settled that "[s]imply doing continuous and systematic business in a state is not enough to establish general jurisdiction." *Addelson*, 2016 WL 6216124 at *3; *see also In re Bard*, 2016 WL 6393596, at *4 ("Plaintiffs identify no Missouri-related contacts by Defendants other than sales and marketing efforts, and the Supreme Court has held that such contacts are not sufficient for general jurisdiction."); *Keeley*, 2015 WL 3999488, at *2 ("Simply marketing and selling a product in a state does not make a defendant's affiliation with the state so 'continuous and systematic as to render them essentially at home in the forum state.'") (quoting *Goodyear*, 564 U.S. at 919); *In re Zofran*,

2016 WL 2349105, at *3 (holding that marketing and selling products in Missouri was insufficient to establish general jurisdiction in Missouri); *Aclin*, 2016 WL 3093246, at *6 (holding that transacting business in Oklahoma was insufficient to establish general jurisdiction in Oklahoma).

B. Bayer Is Not Subject To Specific Personal Jurisdiction For The Non-Missouri Plaintiffs' Claims.

Specific personal jurisdiction applies only if a defendant "has sufficient 'minimum contacts with [the forum state] such that the maintenance of the suit does not offend "traditional notions of fair play and substantial justice."'" *Viasystems*, 646 F.3d at 594 (quoting *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)). Unlike general jurisdiction, specific jurisdiction "focuses on 'the relationship among the defendant, the forum, and the litigation.' " *Keeley*, 2015 WL 3999488, at *3 (quoting *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014)).

For the non-Missouri Plaintiffs, there is no "relationship among the defendant, the forum, and the litigation," and hence no specific jurisdiction. *Id.* This Court has recognized that no specific personal jurisdiction exists where, as here, a plaintiff's alleged injury is not "connected to [the] [d]efendant's contacts with the forum state." *Id.*; *see also Addelson*, 2016 WL 6216124, at *4. Because the 82 non-Missouri Plaintiffs do not allege that they were "prescribed [Essure] in Missouri, purchased [Essure] in Missouri, saw the advertisements [for Essure] in Missouri, or in any way w[ere] injured in Missouri," they cannot invoke specific personal jurisdiction in Missouri. *Keeley*, 2015 WL 3999488, at *3; *see Addelson*, 2016 WL 6216124 at *3-4 (finding no specific jurisdiction because "[t]here are simply no facts connecting [the non-Missouri Plaintiff] to the State of Missouri."); *In re Bard*, 2016 WL 6393596, at *4 (finding no specific personal jurisdiction because "Plaintiffs do not allege that any out-of-state Plaintiff was ever in Missouri, much less that they were subjected to any advertising, doctor recommendation, filter

implants, illness, injury, or medical procedure there."); *In re Zofran*, 2016 WL 2349105, at *5 (finding no specific personal jurisdiction because "the non-Missouri plaintiffs do not allege that they were prescribed Zofran in Missouri, took Zofran in Missouri, or that their children suffered injuries in Missouri. Nor do they allege any facts connecting the conduct of GSK in Missouri, if any, to their own claims."). In short, "[e]ven assuming that [the defendants] purposefully directed their activities at [Missouri], [non-Missouri] Plaintiffs have not met their *prima facie* burden to show that their injuries arose out of those activities." *Aclin*, 2016 WL 3093246, at *5.

Further, the non-Missouri Plaintiffs cannot "piggyback" on the specific jurisdiction that the Missouri Plaintiffs may invoke. Specific personal jurisdiction is, by its nature, *specific* to each particular claims and plaintiffs. *Addelson*, 2016 WL 6216124 at *3 ("The specific personal jurisdiction inquiry must be conducted separately for the claims of each individual plaintiff."); *Bard*, 2016 WL 6393596, at *4 ("This is not a class action. The in-state Plaintiffs are not suing on behalf of the out-of-state Plaintiffs, and cannot establish personal jurisdiction for them."); *see also Sun World Lines, Ltd. v. March Shipping Corp.*, 585 F. Supp. 580, 584-85 (E.D. Mo. 1984). The fact that personal jurisdiction may exist with respect to some plaintiffs' claims does not mean it exists with respect to all plaintiffs' claims. *Addelson*, 2016 WL 6216124 at *3; *see also Seiferth v. Helicopteros Atuneros, Inc.*, 472 F.3d 266, 275 n.6 (5th Cir. 2006) (citing 5B Wright & Miller, *Federal Practice And Procedure: Civil* § 1351, at 299 n.30 (2004)); *Remick v. Manfredy*, 238 F.3d 248, 255 (3d Cir. 2001) ("a conclusion that the District Court has personal jurisdiction over one of the defendants as to a particular claim asserted by [plaintiff] does not necessarily mean that it has personal jurisdiction over that same defendant as to [plaintiff's] other claims."). As this Court, and many others have recognized, it follows *a fortiori* that the existence of specific personal jurisdiction with respect to one plaintiff's claims does not establish specific

personal jurisdiction with respect to another plaintiff's claims. *Addelson*, 2016 WL 6216124 at *3-4; *Bard*, 2016 WL 6393596, at *4; *Level 3*, 2014 WL 50856, at *2; *In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings*, Nos. 14 C 1748; 15 C 11058, MDL No. 2545, 2016 WL 640520, at *5-6 (N.D. Ill. Feb. 18, 2016); *Turi v. Main Street Adoption Servs., LLP*, No. 08-14511, 2009 WL 2923248, at *13 (E.D. Mich. Sept. 9, 2009), *aff'd in part, rev'd in part and remanded on other grounds*, 633 F.3d 496 (6th Cir. 2011). *But see Bradshaw v. Mentor Worldwide, LLC*, 2015 WL 3545192, at *2 (E.D. Mo. June 4, 2015), *appeal dismissed as moot in* No. 15-285, ECF Dkt. 4347332 (8th Cir. Dec. 16, 2015). "The fact that the Plaintiffs have been joined in a single lawsuit does not alter the reality that this case involves [94] different Plaintiffs asserting [94] different [sets of] claims." *Bard*, 2016 WL 6393596, at *4. There is no basis for specific personal jurisdiction over Bayer with respect to the 86 non-Missouri Plaintiffs, and their claims should therefore be dismissed.

II. THE NON-MISSOURI PLAINTIFFS' CLAIMS SHOULD BE DISMISSED UNDER THE DOCTRINE OF FORUM NON CONVENIENS.

The non-Missouri Plaintiffs' claims also should be dismissed under the *forum non conveniens* doctrine. *See DeSirey v. Unique Vacations, Inc.*, No. 4:13 CV 881, 2014 WL 272369, at *1 (E.D. Mo. Jan. 24, 2014) (court may dismiss "when it appears that the convenience of the parties and the interest of justice weigh in favor of adjudicating the action abroad"). Here, the two relevant considerations—the availability of an "adequate alternative forum" and the "balance of private and public interest factors"—favor dismissal. *See id.*

Adequate alternative fora exist because each non-Missouri Plaintiff could bring an action in the state in which she was injured or in which Bayer resides, and Plaintiffs would be treated fairly in such fora. *See De Melo v. Lederle Labs., Div. of Am. Cyanamid Corp.*, 801 F.2d 1058, 1061 (8th Cir. 1986). Moreover, the relevant public and private factors favor dismissal. The

public factors include "the relative ease of access to sources of proof," the "the cost of obtaining attendance of willing . . . witnesses," and "practical problems that make trial of a case easy, expeditious and inexpensive." *Id.* at 1062. Here, access to key witnesses, most notably non-Missouri Plaintiffs' various treating physicians from around the country, will be more easily obtained in the states in which they treated their patients.

The private factors include "[t]he administrative difficulties flowing from court congestion," "the local interest in having localized controversies decided at home," "the interest in having the trial of a diversity case in a forum that is at home with the law that must govern the action," "the avoidance of unnecessary problems in conflict of laws," and "the unfairness of burdening citizens in an unrelated forum with jury duty." *Id.* at 1063. There is no reason to burden this Court with the claims 86 non-Missouri Plaintiffs regarding events that took place entirely outside of Missouri. The states in which the non-Missouri Plaintiffs were allegedly injured have far greater interests in serving as the fora for these claims. Moreover, dismissing the non-Missouri Plaintiffs' claims will avoid the difficulties of applying multiple states' laws, resolving numerous conflict of laws problems, and burdening Missouri citizens with jury duty to decide non-Missouri claims. Thus, the Court also should dismiss the non-Missouri Plaintiffs' claims under the doctrine of *forum non conveniens.*

III. PLAINTIFFS' CLAIMS ARE PREEMPTED.

Plaintiffs' claims are preempted, as other courts have held in dismissing similar Essure claims. *See, e.g.*, *Norman*, 2016 WL 4007547, at *5-6; *De La Paz*, 159 F. Supp. 3d at 1100; *see also Richardson*, 2016 WL 4546369, at *9 (dismissing nine out of ten claims after which plaintiffs voluntarily dismissed with prejudice); *McLaughlin*, 172 F. Supp. 3d at 838-39 (dismissing 10 of 12 claims). Federal law expressly preempts any state-law claim against a medical device manufacturer that would impose safety or effectiveness requirements on a Class

III medical device "different from, or in addition to, any requirement" imposed by FDA through the PMA process. 21 U.S.C. § 360k(a)(1); *Riegel*, 552 U.S. at 321; *In re Medtronic*, 623 F.3d at 1204. Additionally, because the MDA provides that all actions to enforce FDA requirements "shall be by and in the name of the United States," 21 U.S.C. § 337(a), suits by private parties "for noncompliance with the medical device provisions" are impliedly preempted. *Buckman*, 531 U.S. at 349 n.4; *In re Medtronic*, 623 F.3d at 1204.

The Eighth Circuit has squarely held that this leaves only a "narrow gap" between express and implied preemption: "The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *In re Medtronic*, 623 F.3d at 1204 (internal quotation omitted).

Plaintiffs' claims do not fall within this "narrow gap," and are therefore preempted. Plaintiffs allege fourteen separate causes of action,[3] but they boil down to four basic theories: (1) Essure is defectively designed; (2) Bayer made misrepresentations concerning Essure; (3) Bayer inadequately warned of the risks of Essure; and (4) Essure devices were defectively manufactured. All four theories are foreclosed by preemption precedent.

A. Plaintiffs' Claims Asserting Defects In Essure's Design Are Preempted.

Plaintiffs allege that Essure was defectively designed or that its design was unreasonably dangerous. *See, e.g.*, Pet. ¶¶ 1106, 1159, 1167. Claims based on these allegations are preempted because FDA specficially approved the design of Essure, and found that the design is safe and

[3] The claims are: negligence, negligence per se, negligence-misrepresentation, strict liability-failure to warn, manufacturing defect, common law fraud, constructive fraud, fraudulent concealment, breach of express warranty, breach of implied warranty, violation of consumer protection laws, Missouri products liability action, violation of the Missouri Merchandising Practices Act, and gross negligence/punitive damages.

effective. FDA has repeatedly reaffirmed this judgment, including most recently on February 29, 2016. *See supra* at 5.

As *De La Paz* explained, Essure design-defect claims "cannot survive preemption." 159 F. Supp. 3d at 1095. The label of the claim is irrelevant. *See Dishman v. UNUM Life Ins. Co. of Am.*, 269 F.3d 974, 983 (9th Cir. 2001) (plaintiffs cannot escape preemption by merely "dressing up" their claims). The claim is preempted regardless of whether it is characterized as a design defect, a breach of implied warranty, or otherwise. *See De La Paz*, 159 F. Supp. 3d at 1097 (holding implied warranty claim preempted because "[a] determination of whether the Essure device is fit for ordinary use bears directly on its safety and effectiveness," as found by FDA).

B. Plaintiffs' Misrepresentation Claims Are Preempted.

Several of Plaintiffs' claims are based on allegations that Bayer misrepresented Essure's safety and effectiveness in marketing, advertising, and promotions. *See* Pet. ¶¶ 273-76, 448-56.[4] Yet what Plaintiffs characterize as false and misleading statements by Bayer are *actually the same as statements that FDA specifically approved*. There is no substantive difference:

Alleged Misrepresentation by Bayer	Labeling Statement Approved by the FDA
• "zero pregnancies in the clinical trials." *See* Pet. ¶ 273(A).	• "In the original Essure clinical studies, zero (0) pregnancies were reported in women who had the Essure inserts for up to 5 years." *See* RJN Ex. N at 12 (Patient Information Booklet) ("PIB" 2015).

[4] Indeed, *every* count is at least partly based on such allegations. *See, e.g.*, Pet. ¶¶ 992(C), (G), & (J) (negligence); 1013(C), (G), and (J) (negligence per se); 1031 (negligent misrepresentation); 1042(F) (strict liability failure to warn); 1068(C) (strict liability manufacturing defect); 1093 (common law fraud); 1112 (constructive fraud); 1129 (fraudulent concealment); 1133 (breach of express warranty); 1148 (breach of implied warranty); 1154 (violation of consumer protection laws); 1177 (F) (Missouri products liability claim); 6582 (Missouri Merchandising Practices Act); 670 (gross negligence/punitive damages).

• The Essure procedure is "worry free" and a "simple procedure performed in you doctor's office" in "less than 10 minutes," "requires no downtime for recovery," and "eliminates the risks, discomfort, and recovery time associated with surgical procedures." *See* Pet. ¶ 273(B).	• The "benefits of Essure," include that it is "Non-Surgical," that "No General Anesthesia [is] Required," and that "most women return to normal activity within one to two days." *See* RJN Ex. N at 5 (PIB 2015). • "The entire process usually takes less than ten minutes." *See* RJN Ex. N at 9 (PIB 2015).
• "[T]he Essure inserts stay secure, forming a long protective barrier against pregnancy. They also remain visible outside your tubes, so your doctor can confirm that they're properly in place." *See* Pet. ¶ 273(C).	• "Over the next 3 months, your body will form . . . a natural barrier within the fallopian tubes" that "prevents sperm from reaching the eggs." *See* RJN Ex. N at 6 (PIB 2015). • "An Essure Confirmation Test will verify that the inserts are placed correctly so that you can rely on Essure for birth control." *See* RJN Ex. N at 5 (PIB 2015).
• "[T]he Essure inserts are made from the same trusted, silicone free material used in heart stents." *See* Pet. ¶ 273(D).	• "These same materials have been used for many years in cardiac stents and other medical devices placed in other parts of the body." *See* RJN Ex. N at 11 (PIB 2015).
• "Essure is the most effective permanent birth control available, even more effective than tying your tubes or a vasectomy." *See* Pet. ¶ 273(F).	• Essure is "99.83% effective." *See* RJN Ex. N at 5, 10, 12 (PIB 2015). • Comparison of vasectomy, tubal ligation, and other methods of permanent and non-permanent contraception, each listing a higher rate of failure than Essure. *See* RJN Ex. N at 15-19 (PIB 2015).
• "[C]orrect placement . . . is performed easily because of the design of the micro-insert." *See* Pet. ¶ 273(G).	• "Essure is a simple procedure . . . ." *See* RJN Ex. N at 5 (PIB 2015). • "The inserts are soft and flexible, and are delivered with tube through your vagina and cervix, and into your fallopian tubes. No incisions are needed." *See* RJN Ex. N at 6 (PIB 2015).

• "An Essure trained doctor inserts spring-like coils, called micro-inserts" and "[p]hysicians must be signed-off to perform Essure procedure." *See* Pet. ¶¶ 275(A) and (B). • "In order to be trained in Essure you must be a skilled operative hysteroscopist. You will find the procedure easier to learn if you are already proficient in operative hysteroscopy and management of the awake patient. If your skills are minimal or out of date, you should attend a hysteroscopy course before learning Essure." *See* Pet. ¶ 275(D). • "In order to be identified as a qualified Essure physician, a minimum of one Essure procedure must be performed every 6-8 weeks." *See* Pet. ¶ 275(E).	• "The Essure procedure involves placing soft, flexible inserts into your fallopian tubes." *See* RJN Ex. N at 4 (PIB 2015). • "The insert is a dynamic and flexible spring-like device." *See* RJN Ex. L at 1 (2013 IFU). • "This device should only be used by physicians who are knowledgeable hysteroscopists, have read and understood the information in this Instructions for Use and in the Physician Training Manual, and have successfully completed the Essure Training program. Completion of the Essure training program includes preceptoring in Essure placement until competency is established..." *See* RJN Ex. K at 1 (2002 IFU); *see also* RJN Ex. L at 1 (2013 IFU) (similar).
• "The PET fibers are what caused the tissue growth" and Essure "works with your body to create a natural barrier against pregnancy." *See* Pet. ¶ 275(F).	• "It is believed that the tissue in-growth into the device caused by the PET fibers results in both device retention and pregnancy prevention." *See* RJN Ex. K at 4 (2002 IFU). • "PET fiber causes tissue in-growth into and around the insert, facilitating insert retention and pregnancy prevention." *See* RJN Ex. L at 1 (2013 IFU).

As numerous courts have recognized, claims that target "marketing that complied with the FDA-approved requirements" must be dismissed, "because success on [such a] claim[] requires a showing that the FDA requirements themselves were deficient." *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 933 (5th Cir. 2006) (emphasis added); *accord Norman*, 2016 WL 4007547, at *5-6 (dismissing as preempted Essure plaintiff's claims for breach of warranty and negligent misrepresentation because claims were "so similar to the approved language as to be substantively the same"); *De La Paz*, 159 F. Supp. 3d at 1098 (dismissing as preempted Essure plaintiff's claims for "negligent misrepresentation" concerning Essure because "the statements conformed to statements approved by the FDA"); *Pinsonneault v. St. Jude Med., Inc.*,

953 F. Supp. 2d 1006, 1019 (D. Minn. 2013) ("[T]o that extent that plaintiffs' breach of express warranty claims are based on representations stated on an FDA-approved label or on statements that were otherwise approved or mandated by the FDA, such claims are preempted….").

Further, the claims are preempted because the Pet. does not plausibly allege that any asserted federal violation *caused* each Plaintiff's injuries. *See, e.g.*, *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 282 (E.D.N.Y. 2009) (dismissing state law claims as expressly preempted because "in order to survive preemption under the MDA a plaintiff must demonstrate a cognizable link between the defendant's federal violations and the plaintiff's injury"). Instead, like the dismissed plaintiffs' claims in *Norman* and *De La Paz*, Plaintiffs simply assert a laundry list of alleged misrepresentations without describing a "causal link" between any federal requirement and any Plaintiff's injury. *See De La Paz* 159 F. Supp. at 1099; *see also Norman*, 2016 WL 4007547, at *5 (dismissing claims where "plaintiff has not properly alleged any actual misrepresentation, or that she was actually deceived or that she relied on the alleged 'warranty' from the defendants"). Plaintiffs have "failed to allege that [they] ever encountered, much less relied on" any of the specific alleged misrepresentations "made by Bayer in electing to undergo the Essure procedure." *De La Paz* 159 F. Supp. at 1099. Plaintiffs make only conclusory allegations that they "rel[ied] on the misrepresentations and omissions about the safety risks related to Essure in deciding to undergo the Essure procedure," with no allegations as to which of the multitude of supposed misrepresentations were actually read by which Plaintiffs, and how they influenced those Plaintiffs' decisions. Pet. ¶ 1050.

C. Plaintiffs' Failure To Warn Claims Are Preempted.

Plaintiffs' various claims alleging failure to warn are likewise preempted.[5] Like the plaintiffs in *Medtronic*, Plaintiffs here "d[o] not allege that [Bayer] modified or failed to include FDA-approved warnings." 623 F.3d at 1205. Instead, they (1) challenge the FDA-approved labeling as false, misleading, and inadequate, and (2) allege that Bayer failed to report adverse events and other information to FDA. Neither type of claim falls within the "gap" between express and implied preemption under Eighth Circuit law.

1. Claims Challenging The Adequacy Of FDA-Approved Warnings Are Expressly Preempted.

Plaintiffs repeatedly allege that the FDA-approved warnings are "inadequate and insufficient." *See, e.g.*, Pet. ¶¶ 454, 1011 (A) ("the Essure label is false and misleading"), 1013(A) (same), 1042(K) (same), 1054 (referring to Bayer's "inadequate warnings"). But federal law squarely preempts any claim that Bayer "was required to give additional warnings" beyond what FDA approved. *Medtronic*, 623 F.3d at 1205.

As the Eighth Circuit has held, such a direct attack on the FDA approved label is "precisely the type of state requirement that is 'different from or in addition to' the federal requirement and therefore preempted." *In re Medtronic*, 623 F.3d at 1205 (quoting *Riegel*, 552 U.S. at 330); *see also Arthur v. Medtronic, Inc.*, 2014 WL 3894365, at *6 (E.D. Mo. Aug. 11, 2014) (failure to warn claims "alleging that defendants failed to provide adequate warning of the dangers of using the [Class III] device" were expressly preempted); *Blankenship v. Medtronic, Inc.*, 6 F. Supp. 3d 979, 988-89 (E.D. Mo. 2014) (failure to warn claim that would establish

[5] Like the misrepresentation claims, the failure to warn claims are dispersed through the various causes of action, including the first, second, third, fourth, fifth, sixth, eighth, twelfth, thirteenth, and fourteenth causes of action.

different warning and labeling requirement than FDA approved was expressly preempted); *Brooks*, 273 F.3d at 796 ("A jury finding of negligent failure to warn would be premised on the fact that the label . . . was not written in a particular way or did not contain certain information. This would be equivalent to a state regulation imposing specific label requirements."); *Mattingly v. Medtronic, Inc.*, 486 F. Supp. 2d 964, 968 (E.D. Mo. 2007) (similar).

Plaintiffs' allegation that a medical device manufacturer "*may* place into effect" certain labeling changes prior to FDA approval, Pet. ¶ 223 (emphasis added), does not save their claims. As Plaintiffs' phrasing suggests, the regulatory provision at issue is *permissive*, not *mandatory*. *See* 21 C.F.R. § 814.39(d)(1) (providing that certain changes "*may* be placed into effect" before written FDA approval is received) (emphasis added). That distinction is fatal to their claims: "Where a federal requirement permits a course of conduct and the state makes it obligatory, the state's requirement is in addition to the federal requirement and thus is preempted." *In re Medtronic*, 623 F.3d at 1205. Thus, "[e]ven if federal law *allowed* [Bayer] to provide additional warnings . . . any state law *imposing* an additional requirement is preempted by § 360k." *Id.* (emphases in original).

2. Claims That Defendants Failed To Report Adverse Events Are Impliedly Preempted.

Plaintiffs' claims are impliedly preempted to the extent they are based on Bayer's alleged failure to report adverse events or other information to FDA. As the Eighth Circuit has squarely held, allegations that the manufacturer "failed to provide the FDA with sufficient information and did not timely file adverse event reports" are "simply an attempt by private parties to enforce the MDA, claims foreclosed by § 337(a) as construed in *Buckman*." *Medtronic*, 623 F.3d at 1205-06; *Blankenship*, 6 F. Supp. 3d at 989 (noting that a Missouri law failure to warn claim based on "failure to file an adverse event report with the FDA" is preempted under *Buckman* and

Medtronic). That is so because the requirement to report adverse events to FDA does not exist under Missouri law, but rather "exists solely by virtue of the FDCA disclosure requirements." *Buckman*, 531 U.S. at 353; *see also Norman*, 2016 WL 4007547, at *4 ("The failure-to-warn [the FDA] claim arises solely from the MDA's reporting requirements, and therefore is subject to implied preemption."); *Pinsonneault*, 953 F. Supp. 2d at 1017 ("failure to properly or timely . . . warn the FDA . . . is not the type of conduct that would traditionally give rise to liability under state law even if the FDCA had never been enacted.").[6]

Moreover, Plaintiffs' claims are preempted because they do not plausibly allege a "causal link" between any failure to report adverse events and their alleged injuries. *See, e.g.*, *De La Paz*, 159 F. Supp. at 1093, 1099. Plaintiffs never explain how reporting adverse events *to FDA* would have warned *Plaintiffs and their physicians*. *See Norman*, 2016 WL 4007547, at *4 ("[P]laintiff fails to plead facts that plausibly connect defendants' alleged reporting violations to her injuries."). Although Plaintiffs allege that Essure would have been withdrawn from the market had Bayer reported adverse events, *see* Pet. ¶¶ 1046, 1117, 1125, the undisputed facts are that FDA is now aware of all of these alleged adverse events and decided *not* to require Essure's withdrawal. Instead, on February 29, 2016, the FDA reaffirmed that "Essure remains an appropriate option for the majority of women seeking a permanent form of birth control." RJN, Ex. E (FDA News Release (Feb. 29, 2016)).

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[6] *See also Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 860 (W.D. Tenn. 2015) ("to the extent that Plaintiffs seek recourse for Defendants' failure to file adverse event reports with the FDA, the Court finds such claim impliedly preempted under *Buckman*"); *McClelland v. Medtronic, Inc.*, 944 F. Supp. 2d 1193, 1200 (M.D. Fla. 2013) (dismissing as preempted plaintiff's claim "that Defendant violated the FDCA . . . by failing to inform the FDA about [adverse] incidents," and rejecting plaintiff's "attempt to recast [the] claim for violation of the FDCA as a state-law negligence claim"); *Purchase v. Advanced Bionics, LLC*, 896 F. Supp. 2d 694, 697 (W.D. Tenn. 2011) (noting that "claims premised on reporting requirements are disguised fraud-on-the-FDA claims and, therefore, impliedly preempted").

D. Plaintiffs' Manufacturing Defect Claims Are Preempted.

Plaintiffs also bring claims on the theory that their Essure devices were defectively manufactured. These claims are similarly preempted, because Plaintiffs once again seek to second-guess the FDA, which determined that Essure is safe and effective. *See supra at* 5; RJN, Ex. G at 4 (FDA, Premarket Approval Order for the Essure System).

Insofar as Plaintiffs are alleging that Bayer deviated from FDA's manufacturing requirements and that Essure is therefore "adulterated," *see, e.g.*, Pet. ¶ 1086, their conclusory allegations fail for the same reasons that virtually identical allegations failed in *De La Paz*, *Richardson*, and *McLaughlin*. *De La Paz*, 159 F. Supp. 3d at 1094-95; *Richardson*, 2016 WL 4546369, at *4-5; *McLaughlin*, 172 F. Supp. 3d at 834-36. Plaintiffs "cannot state a claim based solely on Bayer's adulteration of certain Essure devices, since any such claim would 'exist solely by virtue of the [MDA],'" and is therefore impliedly preempted. *De La Paz*, 159 F. Supp. 3d at 1094-95 (quoting *Buckman*, 531 U.S. at 353); *see also Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (affirming dismissal of state-law claim as impliedly preempted because "whether the [devices] were modified so that they were 'adulterated' . . . rest[s] within the enforcement authority of the FDA, not this Court"); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir. 1994) (same); *Cornwell v. Stryker Corp.*, No. 1:10-cv-00066, 2010 WL 4641112, at *4 (D. Idaho Nov. 1, 2010) ("To the extent Plaintiff's parallel claim is based on a theory the medical device implanted in Plaintiff was 'adulterated' such claim must also be dismissed as there is no private right of action for the enforcement of federal regulations relating to medical device provisions.").

Plaintiffs' claims are also expressly preempted because they fail to identify violations of federal requirements that produced defects in their devices and caused their injuries. "In order to avoid preemption on a manufacturing defect claim, [a] plaintiff must allege that her device was

not manufactured in conformance with the specification approved by the FDA," *Norman*, 2016 WL 4007457, at *3, and that such deviation "resulted in a manufacturing defect that *caused her injuries*," *De La Paz*, 159 F. Supp. 3d at 1094 (emphasis added). *See also, e.g.*, *Cohen v. Guidant Corp.*, No. CV-05-8070, 2011 WL 637472, at *2 (C.D. Cal. Feb. 15, 2011) (claims preempted where plaintiff failed to "link[]" federal requirements "to a defect in his specific pacemaker that was caused by Defendants violating FDA regulations"). Plaintiffs do not meet this standard. Here, as in *Norman* and *De La Paz*, Plaintiffs provide:

- "no description of the 'non-conforming material' used in manufacturing the device, or how the use of that material caused a defect in the product itself," *De La Paz*, 159 F. Supp. 3d at 1095,
- no "explanation of the function of 'pre-sterile and post-sterile cages' in the manufacturing process," *id.*,
- no "explanation for how Bayer's alleged operation without a license led to any manufacturing defect," *id.*,
- no "plausible reason to think that [their] device[s] came from [a] non-conforming batch, or that [they] suffered from any other manufacturing defect," *Norman*, 2016 WL 4007457, at *3, and
- no "facts that would make it plausible that the complications [they] suffered . . . were due to any defect in the device," *id.*

Accordingly, as in *Norman* and *De La Paz*, Plaintiffs' claims fail.

Finally, Plaintiffs' other conclusory assertions of manufacturing defects—including failure to comply with "general quality control standards," "quality problems," and other unspecified "device failures"—are also expressly preempted. A manufacturing defect claim must be based on failure to follow a "specific federal requirement in the PMA approval." *In re Medtronic*, 623 F.3d at 1206. But every manufacturing "requirement" Plaintiffs identify is actually an FDA Current Good Manufacturing Practice ("CGMP"). *See* Pet. ¶¶ 1011, 1032,

1096 (listing provisions from 21 C.F.R. Part 820).[7] As the Eighth Circuit held in *Medtronic*, CGMPs are merely an "umbrella quality system" providing "general objectives" for manufacturers—not "specific federal requirement[s] in the PMA approval"—and thus "do not save . . . claims from preemption." *In re Medtronic*, 623 F.3d at 1206; *see also Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 588 (E.D.N.Y. 2009) (CGMPs too "intentionally vague and open-ended" to save claims from preemption); *Horowitz*, 613 F. Supp. 2d at 284 (CGMPs "too generic" to save claims from preemption).

IV. PLAINTIFFS FAIL TO PLEAD A PLAUSIBLE CLAIM FOR RELIEF.

Even if Plaintiffs' claims are not preempted—and they are—they also should be dismissed because Plaintiffs fail to articulate "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); Fed. R. Civ. P. 8; *see also Horras v. Am. Capital Strategies, Ltd.*, 729 F.3d 798, 801 (8th Cir. 2013) (a complaint cannot rely on "labels and conclusions," a "formulaic recitation of the elements of a cause of action," or "naked assertions devoid of further factual enhancement" (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)) (internal quotations omitted). Further, Plaintiffs fail to plead their fraud-based claim with the requisite particularly. *See* Fed. R. Civ. P. 9(b).

A. Plaintiffs Fail To Plead Facts To Show Causation Or Reliance.

Plaintiffs' failure to allege a causal link between asserted federal violations and their injuries dooms the Petition under *Twombly* and *Iqbal*. The Petition impermissibly bases claims on conclusory allegations that Plaintiffs "relied" on "Defendant's representations and

[7] Several of the statutory and regulatory provisions that Plaintiffs list in their negligence, negligence per se, and strict liability manufacturing defect claims concern alleged misrepresentations or failure to report adverse events. *See, e.g.*, 21 U.S.C. §§ 352(a), 331(a), 352(q), 360i(a), 360(q), 360(r); 21 C.F.R. §§ 803.50, 814.80, 814.84(b)(2), 803.3, 814.39.

omissions," "would not have consented to undergo the Essure procedure" had they known "the true increased risks, hazards, and serious dangers of Essure," and were injured by "one or more" of various federal violations. *See, e.g.*, Pet. ¶¶ 457-58, 1012, 1033, 1097. Courts routinely find that such allegations are not sufficient to allege causation in product liability cases. *See, e.g.*, *McLaughlin*, 172 F. Supp. 3d at 836 ("[The complaint] does not allege that any [Essure] device affected by these errors was implanted in any of the [p]laintiffs, much less that any such manufacturing errors actually caused [the] [p]laintiffs' injuries."); *De La Paz*, 159 F. Supp. 3d at 1095 ("De La Paz's claims also fail because she offers only conclusory allegations that the alleged irregularities caused her injuries."); *Hawkins v. Medtronic, Inc.*, No. 1:13-cv-00499, 2014 WL 346622, at *8 (E.D. Cal. Jan. 30, 2014) ("Plaintiff generally alleges that Defendants failed to report adverse events to the FDA. He also generally alleges that these failures caused or contributed to his injuries. What is not alleged is any factual content that would support the causal nexus. . . . Thus, claims based on Defendants' failure to report adverse event[s] to the FDA cannot stand because they are not adequately pled."); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008) ("The complaint does allege generally that the [device] was unreasonably dangerous and defective . . . , which proximately caused plaintiff's injuries. However, such conclusory allegations standing alone are not sufficient to sustain plaintiff's burden of pleading under *Twombly*.").

B. Plaintiffs Fail To Plead Fraud With Particularity.

Plaintiffs also fail to plead negligent misrepresentation, common law fraud, constructive fraud, fraudulent concealment, consumer protection, and Missouri Merchandising Practice Act ("MMPA") with the requisite particularity. *See* Fed. R. Civ. P. 9(b); *Blake v. Career Educ. Corp.*, No. 4:08-cv-0821, 2009 WL 140742, at *2 (E.D. Mo. Jan. 20, 2009) (Rule 9(b) applies to MMPA, consumer fraud statutes, and common law fraud claims). Plaintiffs "d[o] not allege

specific facts showing that they relied" on the alleged misrepresentations. *In re NationsMart Corp. Sec. Litig.*, 130 F.3d 309, 322 (8th Cir. 1997). Nor do they "claim that they ever read" the alleged misrepresentations or "specify which allegedly fraudulent statements they relied on in purchasing" Essure. *Id.* Plaintiffs' fraud-based claims must therefore be dismissed for this additional reason.

CONCLUSION

For these reasons, this Court should grant Bayer's motion to dismiss Plaintiffs' claims.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of March, 2017, a true and correct copy of the foregoing document was served upon the following via the Court's electronic notification system, electronic mail, and/or U.S. Mail, postage prepaid:

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